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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development

Submission for OMB review; comment request

Provider-Based Sampling Feasibility Study for the Vanguard (Pilot) Study and Data Collection Updates for the National Children's Study (NICHD)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Child Health and Human Development (NICHD), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on January 30, 2012, pages 4569 – 4571, and allowed 60 days for public comment. No written comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

PROPOSED COLLECTION:

Title: Provider-Based Sampling Feasibility Study for the Vanguard (Pilot) Study and Data Collection Updates for the National Children's Study (NICHD)

The National Children's Study, Vanguard (Pilot) Study

Type of Information Collection Request: Revision

Need and Use of Information Collection:

The purpose of the proposed methodological study is to continue the Vanguard phase of the National Children's Study with updated instruments and additional biospecimen collections and physical measures and to evaluate the feasibility, acceptability, and cost of a different sampling strategy for enrollment of pregnant women.

This study is one component of a larger group of studies being conducted during the Vanguard Phase of the National Children's Study (NCS), a prospective, national longitudinal study of child health and development. In combination, these studies will be used to inform the design of the Main Study of the National Children's Study.

BACKGROUND:

The National Children's Study is a prospective, national longitudinal study of the interaction between environment, genetics on child health and development. The Study defines "environment" broadly, taking a number of natural and man-made environmental, biological, genetic, and psychosocial factors into account. Findings from the Study will be made available as the research progresses, making potential benefits known to the public as soon as possible.

The National Children's Study (NCS) has several components, including a pilot or Vanguard Study, and a Main Study to collect exposure and outcome data. The sample frame for the NCS Vanguard and Main Study was initially based on a national probability sample using geography as the basis and selecting about 100 of the about 3,000 counties in the United States as the basis for Primary Sampling Units. Within the Primary Sampling Units, smaller geographic segments were selected as Secondary Sampling Units in an attempt to normalize live birth rates per area sampled. Women who resided at the time of enrollment within a designated Secondary Sampling Unit and were either pregnant or between 18 and 49 were eligible for enrollment. The initial recruitment technique within the selected geographic areas was household contact by field workers going door to door.

The Vanguard Study was launched in January 2009 and, by the summer of 2009, field experience suggested that the household contact recruitment strategy was not feasible with available resources. Thus, in 2010, new recruitment strategies were launched to evaluate options. By late 2011, the NCS had sufficient data to evaluate operational aspects of various recruitment strategies. Preliminary analyses suggested that a Provider-Based Recruitment strategy was the most efficient, but due to constrictions of the geographic sampling frame, the potential of the strategy was limited. Specifically, many women had to be screened at a particular provider to locate the relatively few who

resided in a designated segment. Anticipating this limitation, the NCS Program Office developed and discussed with the NCS Federal Advisory Committee a different sampling frame using provider location. This new sampling strategy is termed Provider-Based Sampling (PBS). Information from this data collection is critical to determine the plausibility of a provider-based sampling frame as an option for some parts of the NCS Main Study.

RESEARCH QUESTIONS:

Two research goals will be accomplished by this information collection. One goal is to test the feasibility of Provider-Based Sampling using three study locations. Another goal is to systematically pilot additional study visit measures and collections to assess the scientific robustness, burden to participants and study infrastructure, and cost for use in the Vanguard (Pilot) Study and to inform the design of the Main Study.

METHODS:

Provider Based Sampling

We will compile, a list of prenatal providers serving women who reside within the Primary Sampling Unit at three study locations. Providers will be asked to complete a brief questionnaire about their practice and their patient demographics. For this pilot, a woman will be eligible for recruitment if she resides in the Primary Sampling Unit and is seeing a provider for her first prenatal visit.

Recruitment of participants at the selected provider offices will largely follow the protocol and procedures developed for the Provider-Based Recruitment Substudy, as previously approved by the Office of Information and Regulatory Affairs within the Office of Management and Budget. Potential participants will be screened on age eligibility, residence in the sampled Primary Sampling Unit, and pregnancy status at the initial prenatal visit. In some locations, medical records may be pre-screened to identify participants meeting these eligibility criteria.

Supplemental Information and Biospecimen Collections

We will continue data collection with pregnancy and birth periods, as well as postnatal data collection points at 3, 6, 9, 12, 18, and 24 months of age. We propose to

add or modify the selected measures below to address analytic goals of assessing feasibility, acceptability and cost of specific study visit measures.

Core Questionnaire: We propose to pilot a Core Questionnaire containing key variables and designed to collect core data at every study visit contact from the time that the enrolled child is 6 months of age to the time the child is 5 years of age.

30-Month Data Collection Module: We propose piloting an age-specific module alongside of the Core Questionnaire with the 30-Month Interview.

Validation Questions for 18, 24 and 30 Month: We propose addition of brief, telephone-based questions that would be fielded to a random sample of each interviewer's cases after completion of the 18-Month, 24-Month, and 30-Month interviews to monitor interviewer performance and identify occurrences of data falsification.

Nonrespondent Questionnaire: We will collect information on why a participant chose to not enroll or withdraw from the NCS. This information may be used to revise our approaches to recruitment and will help the Study frame other systematic analyses of nonresponse bias.

Physical Measures: The addition of 6 month, 12, and 24-Month infant measures of child anthropometry and/or blood pressure may provide critical pieces of information for future research on the causes of obesity, diabetes, premature puberty and a host of other health outcomes.

Revised Father Questionnaire: We seek to incorporate behavioral, emotional, educational and contextual consequences to enable a complete assessment of psychosocial influences on children's well-being. The revised Father Questionnaire now includes measures addressing key social/personal resources and fathers' capacity, desire and attitudes towards engaging with mothers and children.

Additional Instrument at the 24-Month Interview: The Modified Checklist for Autism in toddlers (M-CHAT™) is a validated brief screening measure for identification of Autism and will be added to the 24-Month Interview.

Breast Milk Collection 1 and 3 Months: Additional collections are needed to determine the feasibility, acceptability and cost of collection.

Infant Urine Collection at 6- and 12-Month Visits: Additional collections are needed to determine the feasibility, acceptability and cost of collection.

Infant Blood and Saliva Collection at the 12-Month Visit: Additional collections are needed to determine the feasibility, acceptability and cost of collection.

Frequency of Response: See above descriptions.

Affected Public: Healthcare providers, pregnant women, fathers, and their children. The additional annualized cost to respondents over the three-year data collection period is estimated at annualized cost of \$229,804. This is calculated as estimating 31,082 respondent contacts at an estimated average of 0.73 hours per contact, for a total estimated annual respondent burden as 22,791 hours. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Data Collection Activity	Type of Respondent	Estimated Number of Respondents	Estimated Number of Responses per Respondent	Average Burden Per Response (in hours)	Estimated Total Annual Burden Hours	Estimated Total Annual Respondent Cost
Screening Activities						
Provider Based Sampling Eligibility Screener (PBS)	Pregnant Women	3,125	1	20/60	1,042	\$10,417
Provider Based Sampling Frame Questionnaire (PBS)	Healthcare Providers	50	1	25/60	21	\$2,104

Data Collection Activity	Type of Respondent	Estimated Number of Respondents	Estimated Number of Responses per Respondent	Average Burden Per Response (in hours)	Estimated Total Annual Burden Hours	Estimated Total Annual Respondent Cost
Continuous Activities						
Nonrespondent Questionnaire (PB, EH, TT-HI, TT-LI, PBS)	Pregnant Women, Mothers or Fathers	480	1	5/60	40	\$400
Validation Interview - up to 30 Months (PB, EH, TT-HI, TT-LI, PBS)	Respondents	1,268	1	5/60	106	\$1,057
Participant Verification (PB, EH, TT-HI, TT-LI, PBS)	Pregnant Women, Mothers or Fathers	2,320	1	5/60	193	\$1,933
Tracing Interview (PB, EH, TT-HI, TT-LI, PBS)	Respondents	1,167	13	10/60	2,528	\$25,281
Pregnancy Activities						
Low-intensity Questionnaire (Found Pregnant) (TT-LI)	Pregnant Women	173	1	15/60	43	\$432
Pregnancy Visit 1 Interview (PB, EH, TT-HI, PBS)	Pregnant Women	2,018	1	35/60	1,177	\$11,774
Pregnancy Visit 2 Interview (PB, EH, TT-HI, PBS)	Pregnant Women	1,817	1	25/60	757	\$7,569
Biological and Environmental Sample Collection - Prenatal (PB, EH, TT-HI)	Pregnant Women	1,456	2	60/60	2,913	\$29,127
Pregnancy Health Care Log (PB, EH, TT-HI, PBS)	Pregnant Women	1,615	1	20/60	538	\$5,382
Father Interview (PB, EH, TT-HI)	Alternate Caregiver	818	1	35/60	477	\$4,770
Birth-Related Activities						

Data Collection Activity	Type of Respondent	Estimated Number of Respondents	Estimated Number of Responses per Respondent	Average Burden Per Response (in hours)	Estimated Total Annual Burden Hours	Estimated Total Annual Respondent Cost
Birth Visit Interview (PB, EH, TT-HI, PBS)	Mother / Baby	1,141	1	20/60	380	\$3,802
Low-intensity Questionnaire (Birth-focus) (TT-LI)	Mother / Baby	432	1	15/60	108	\$1,080
Postnatal Activities						
Infant Feeding Log (PB, EH, TT-HI, PBS)	Mother / Baby	1,106	1	20/60	369	\$3,688
Biological Sample Collection - Mother/Baby (PB, EH, TT-HI)	Mother / Baby	761	4	22.5/60	1,141	\$11,411
3-Month Interview (PB, EH, TT-HI, TT-LI, PBS)	Mother / Baby	1,518	1	20/60	506	\$5,061
6-Month Interview (PB, EH, TT-HI, PBS)	Mother / Baby	1,066	1	30/60	533	\$5,331
Physical Measures - Child Anthropometry (6-,12-,24-Month) (PB, EH, TT-HI)	Baby / Child	701	3	20/60	701	\$7,014
Physical Measures - Child Blood Pressure (12-,24-Month) (PB, EH, TT-HI)	Baby / Child	675	2	10/60	225	\$2,250
9-Month Interview (PB, EH, TT-HI, TT-LI, PBS)	Mother / Baby	1,428	1	10/60	238	\$2,381
12-Month Interview (PB, EH, TT-HI, PBS)	Mother / Baby	1,003	1	50/60	836	\$8,360
18-Month Interview (PB, EH, TT-HI, TT-LI, PBS)	Mother / Child	1,316	1	30/60	658	\$6,582

Data Collection Activity	Type of Respondent	Estimated Number of Respondents	Estimated Number of Responses per Respondent	Average Burden Per Response (in hours)	Estimated Total Annual Burden Hours	Estimated Total Annual Respondent Cost
24-Month Interview (PB, EH, TT-HI, TT-LI, PBS)	Mother / Child	1,251	1	35/60	729	\$7,295
Core Questionnaire (PB, EH, TT-HI, TT-LI, PBS)	Mother / Child	1,188	1	30/60	594	\$5,940
30-Month Visit Interview (PB, EH, TT-HI, TT-LI, PBS)	Mother / Child	1,188	1	55/60	1,089	\$10,890
Total, Vanguard (Pilot) Study		31,082			17,943	\$181,331
Total, Formative Research					4,847	\$48,473
Grand Total		31,082			22,791	\$229,804

REQUEST FOR COMMENTS: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to Office of Management and Budget, Office of Information and Regulatory Affairs, Attn: NIH Desk Officer, by E-mail to OIRA_submission@omb.eop.gov, or by fax to 202-395-6974. To request more information on the proposed project or to obtain a copy of the data collection plans and

instruments, contact Ms. Jamelle E. Banks, Public Health Analyst, Office of Science Policy, Analysis and Communication, National Institute of Child Health and Human Development, 31 Center Drive Room 2A18, Bethesda, Maryland, 20892, or call a non-toll free number (301) 496-1877 or E-mail your request, including your address to banksj@mail.nih.gov.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: April 16, 2012

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